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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,998	09/18/2003	J. Oliver Dolly	17259-CON (B07)	1940
7590	07/12/2007			
Carlos A. Fisher ALLERGAN, INC. T2-TH 2525 Dupont Drive Irvine, CA 92612			EXAMINER FALK, ANNE MARIE	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 07/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/667,998	<b>Applicant(s)</b> DOLLY ET AL.	
	<b>Examiner</b> Anne-Marie Falk, Ph.D.	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

The amendment filed June 26, 2007 has been entered. Claims 1 and 5 have been amended.

The elected invention is directed to a method for extending the effective time period during which tissue treated with a clostridial toxin is paralyzed comprising administering a composition comprising an agent able to prevent the neuroregenerative activity of a polypeptide as recited in the claims (various neurotrophic factors). Applicants further elected the species IGF-1, from among the various polypeptides, and the species of a binding protein other than an antibody, from among the various agents.

Claims 1-5 and 26 remain pending and are examined herein.

Prosecution of this application is reopened in view of the new rejection set forth below.

The objection to Claims 1-5 and 26 set forth at page 3 of the Office Action of 6/20/07 is withdrawn in view of the amendments to the claims.

The rejection of Claims 1-5 and 26 under 35 U.S.C. 112, second paragraph, for indefiniteness, is withdrawn in view of the amendments to the claims.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

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owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caroni et al. (1994, J. Cell Biol. 125(4): 893-902, cited on IDS filed 9/18/03) and Coffield et al. (1994, Neurological Disease and Therapy, pp. 3-13, cited on IDS filed 9/18/03)

Caroni et al. (1994) disclose *in vivo* experiments where local delivery of IGF-BP4 to botulinum toxin A-paralyzed skeletal muscle of mice effectively prevented nerve sprouting in that muscle. Balb/C mice were paralyzed locally with a single injection of botulinum toxin A into one gluteus muscle (page 894, column 2, paragraph 4). The reference further discloses that paralysis is known to induce neurite outgrowth promoting activity and that this activity is blocked by local administration of IGF-BP4 (page 895-898). The authors concluded that muscle IGFs play an essential role in intramuscular nerve sprouting. The reference further discloses that IGF-BPs can be applied as pharmacological agents to interfere with the activity of IGFs *in vivo* (page 900, column 2, last paragraph).

Coffield et al. (1994) disclose various medicinal uses of botulinum neurotoxin and discusses the mechanism of action. At page 10, the reference notes that it would be desirable to have an agent that exerts its effects for a longer duration.

In view of the teachings of Coffield et al. regarding the medicinal uses of botulinum neurotoxin to effect paralysis of target muscle tissue and the teaching of Caroni et al. that local delivery of IGF-BP4 to muscle paralyzed by administration of botulinum toxin A effectively prevents nerve sprouting in that muscle, one of skill in the art would readily recognize that administration of IGF-BP4 in combination with botulinum neurotoxin would extend the period of time that paralysis is maintained, as compared to

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administration of botulinum neurotoxin alone, by preventing restoration of nerve function that occurs with nerve sprouting. Thus, preventing nerve sprouting and the accompanying restoration of nerve function by the administration of IGF-BP4 would be expected to extend the period of paralysis as compared to the use of botulinum neurotoxin alone.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

No claim is allowable.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/  
Primary Examiner, Art Unit 1632